EXHIBIT 6

PCT ORGANISATION MONDIALE DE LA PROPRIETE INTELLECTUELLE
Bureau international

DEMANDE INTERNATIONALE PUBLIEE EN VERTU DU TRAITE DE COOPERATION EN MATIERE DE BREVETS (PCT)

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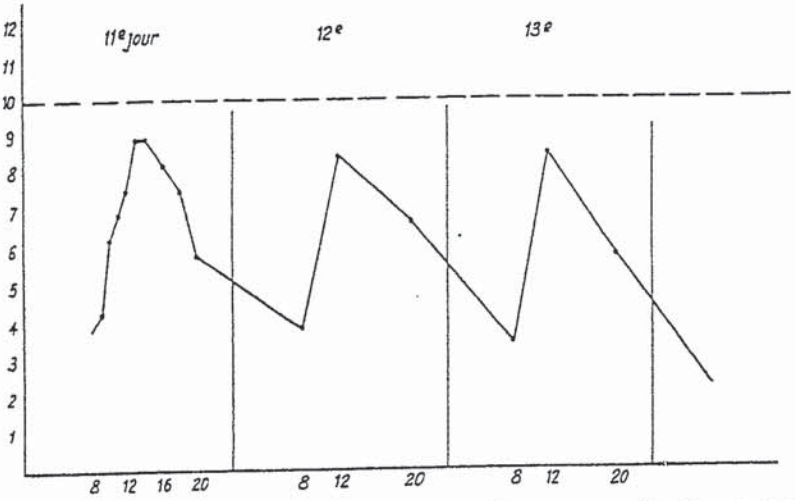
(54) Title: NEW GALENIC PREPARATION OF PHENOFIBRATE, METHOD FOR THE OBTENTIO N THEREOF, ITS APPLICATION AS A MEDICINE

(54) Titre: NOUVELLE FORME GALENIQUE DU FENOFIBRATE, SON PROCEDE D'OBTENTION, SON APPLICATION COMME MEDICAMENT

(57) Abstract

The medicine is formed with granules, each of them being comprised of a neutral core (saccharose + starch) covered with a first layer of phenofibrate admixed with an excipient, and with a second microporous outer layer of an edible polymer. The daily administration of one capsule of 250 mg instead of three doses of 100 mg allows to reduce the dosing and the number of administrations due to the progressive and retarded release of the phenofibrate. A minimum dose is maintained in the blood, high temporary concentrations are avoided and the total ingested quantity is reduced.



(57) Abrégé

Le médicament est formé de granules constituées chacune d'un noyau neutre (saccharose + amidon) recouvert d'une première couche de fénofibrate en mélange avec un excipient, et d'une deuxième couche extérieure microporeuse d'un polymère comestible. L'administration d'une gélule de 250 mg par jour au lieu de trois prises de 100 mg permet ainsi de réduire le dosage et le nombre d'administrations grâce à la libération progressive et retardée du fénofibrate. On maintient une dose minimale dans le sang, on évite les fortes concentrations temporaires, et on réduit la quantité totale ingérée.

EXHIBIT 7

European Patent Office

EP 0 793 958 A2

EUROPEAN PATENT APPLICATION

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IPC7: A61K 9/16

Application No.: 97103306.3

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Process for Preparing a Composition Containing Fenofibrate

The subject of the invention is a process of producing fenofibrate preparations using fenofibrate, surface-active agents and polyvinylpyrrolidone as well as, optionally, 1 or more other adjuvants and

using a mixing and a granulating and a subsequent drying, that is by which in that at first fenofibrate particles are mixed with polyvinylpyrrolidone particles and cross-linked polyvinylpyrrolidone particles as well as, optionally, other adjuvant particles, and then the mixture obtained is granulated with an aqueous solution of 1 or more surface-active agents in a constituent amount of at least 1.5 wt% relative to the dry granulate to be produced, and the granulate is dried.

Said process is simpler than those known in the art und leads nevertheless to products with approximately equally good therapeutic action as those obtained according to the state of the art.

Specification

The invention relates to a process of producing fenofibrate preparations with which fenofibrate preparations can be readily obtained with approximately equally good bioavailability and, as a consequence, equally good action as those produced in accordance with the state of the art.

Fenofibrate with the chemical designation 2-(4'-[4"-(chloro)-benzoyl]phenoxy)-2-(methyl)-propionic acid isopropylester is a known lipid reducer.

EP patent 330 532 teaches a process of producing fenofibrate preparations in which

(i) The fenofibrate and a solid, surface-active agent are intimately mixed and subsequently subjected to a common treatment with a jet mill,

(ii) Lactose and starch are added to the mixture obtained,

(iii) The entirety is granulated in the presence of water and

(iv) Granulated until a granulate containing at the most 1% water is obtained,

(v) The granulate is calibrated and

(vi) Polyvinylpyrrolidone and magnesium stearate are added.

It is stated that in order to increase the bioavailability of the fenofibrate, the common grinding (co-micronization) of fenofibrate and surface active agent is essential (Page 2, lines 21 to 22).

Furthermore, DE patent 35 03 681 describes a swellable polymer that is insoluble in water and is charged with a biologically active substance or a substance that is converted into one in vivo, obtainable by producing and grinding a mixture of this substance with a swellable polymer that is insoluble in water in a weight ratio of the cited substance : polymer of 1 : 0.1 to 1 : 100, which polymer can be cross-linked polyvinylpyrrolidone or cross-linked sodium carboxymethylcellulose.

Moreover, drugs are known from DE patent 31 52 519 that have a delayed release for oral administration, containing an active-substance layer with binding agents and containing a water-permeable, porous jacketing whose neutral core consists of inert binding agents selected from the group of raw sugar and lactose, optionally starch, and in which the neutral core is jacketed with a first layer containing active substance containing fenofibrate and/or its derivatives in a mixture with a binding agent from the group of talcum, silicon dioxide or their mixtures as well as stearic acid, and the granules comprise a second, outer layer formed from a microporous jacket, among other things with polyvinylpyrrodidone.

Furthermore, EP-A1-256 933 describes a process for producing a medicament in granular form in which in one stage a neutral core is moistened with an external, moist, adhesive layer that can be, among other things, based on polyvinylpyrrolidone, and then in another stage fenofibrate microparticles are applied onto the moistened core, advantageously by spraying, and the entirety is dried.

US patent 4, 800, 079 and 4, 961, 890 and FR-A1-2 602 423 relate to approximately the same process.

FR-A1-2 617047 teaches a fenofibrate preparation containing fenofibrate and a surface-active agent as well as dimethylisosorbide and optionally a gelling agent and excipients in capsules.

Moreover, GB patent 931 147 teaches a process of producing a retarding preparation by melting polyvinylpyrrolidone, fatty acids and the like and an active substance, forming droplets from the melt, spraying and forming pellets.

Furthermore, US patent 4, 925, 672 describes a combination of verapamil and fenofibrate of which the fenofibrate part can also contain polyvinylpyrrolidone. Nothing is stated about the process.

Furthermore, preparation No. 58 029 (Normalip pro®) capsules are described in the "Rote Liste" [German – "Red List") 1996 containing micronized fenofibrate, cross-linked polyvinylpyrrolidone (crospovidone) and sodium dodecylsulfate. The process of manufacture is not indicated but

it is known in professional circles that the manufacture takes place in accordance with the process of EP patent 330 532 discussed above.

The invention is based on the problem of creating fenofibrate preparations using fenofibrate, surface-active agents and polyvinylpyrrolidone as well as, if necessary, other adjuvants and using a mixing and a granulation and subsequent drying, by means of which process fenofibrate preparations with approximately equally good therapeutic action as those obtained according to the state of the art can be obtained in a manner that is surprisingly simpler than in the state of the art.

The above was surprisingly achieved in accordance with the invention without a common grinding of fenofibrate and solid surface-active agents.

The invention has as subject matter a process for producing fenofibrate preparations using fenofibrate, surface-active agents and polyvinylpyrrolidone as well as, optionally, 1 or more other adjuvants and using a mixing and a granulating and a subsequent drying, that is characterized in that at first fenofibrate particles are mixed with polyvinylpyrrolidone particles and cross-linked polyvinylpyrrolidone particles as well as, optionally, other adjuvant particles, and then the mixture obtained is granulated with an aqueous solution of 1 or more surface-active agents in a constituent amount of at least 1.5 wt% relative to the dry granulate to be produced, and the granulate is dried.

~~Micronized matter is preferably used as fenofibrate [sic — this appears to mean "The fenofibrate used is micronized"?]~~

Preferably fenofibrate is used under a micronized form.

Compared to the teaching of EP patent 330 532 that has to carry out a common grinding of fenofibrate and a solid surface-active agent for achieving optimal bioavailability, it is surprising that this can be achieved by the invention even without the above in that the separately ground fenofibrate is merely mixed with polyvinylpyrrolidone and cross-linked polyvinylpyrrolidone without grinding and this mixture is granulated with the surface-active agent placed in aqueous solution and that it is not the case that the granulation takes place only after the introduction of the surface-active agent.

The polyvinylpyrrolidone present with the fenofibrate makes possible the construction of a granulate structure during the spraying with the solution of the surface-active agent or agents. It can be assumed that this also brings about a hydrophilization of the fenofibrate, which results in a better resorption and therewith an increasing of the bioavailability. The minimum amount of the surface-active agent or agents is critical since no satisfactory therapeutic result could be achieved below 1.5 wt%. The engineering simplification of the process in accordance with the invention compared to EP patent 330 532 resides primarily in the fact that according to the invention all adjuvants can be mixed in one and the same stage with the fenofibrate whereas in the cited, known process the other adjuvants must obligatorily be mixed in in an additional, separate stage on account of the obligatorily prescribed, common grinding (co-micronization) of the

fenofibrate and of the solid, surface-active agent. Furthermore, in the process of the invention the micronization alone of the fenofibrate brings about a reduction of the micronization volume compared to the common micronization of fenofibrate and of solid, surface-active agent and therewith brings about a lesser consumption of energy.

The process in accordance with the invention also differs basically from DE patent 35 03 681 in that in contrast to the common grinding of active substance and adjuvants described in it such as cross-linked polyvinylpyrrolidone (Claim 1, page 2, lines 23 to 33 and page 3, lines 34 to 37) with the assertion that the reduction of the particle size of drugs is frequently not effective enough when they are separately ground (page 2, lines 7 to 10), as already stated, a separate grinding of fenofibrate takes place and the ground fenofibrate is mixed only physically with the adjuvants. Furthermore, in contrast to DE patent 35 03 681 with the use of only a polymer that is insoluble in water, in the process of the invention the using of water-soluble polyvinylpyrrolidone for mixing with fenofibrate is indispensable for solving the problem posed. Also, in the process of the invention the granulating is performed with a surface-active agent that is not used at all in the cited publication.

Moreover, the product characteristics are also different in that in the process of DE patent 35 03 681 and EP patent 330 532 during the common grinding of active substance and adjuvants an amorphization of the active substance takes place whereas during the mere mixing in the process of the

invention the fenofibrate remains crystalline, as our own tests showed with a comparison of non-ground fenofibrate and only ground fenofibrate.

In contrast to DE patent 31 52 519 according to which the fenofibrate and the polyvinylpyrrolidone are present at different locations, namely, the first one in the first layer and the latter one in the external layer, and in which there is no mention of the two being mixed, in the process of the invention a mixing of the fenofibrate particles with polyvinylpyrrolidone particles and in addition with cross-linked polyvinylpyrrolidone particles takes place. The cited publication makes no mention of using cross-linked polyvinylpyrrolidone and a surface-active agent. According to its process cross-linked polyvinylpyrrolidone can not be used at all because, according to page 3, lines 5 to 51, the polymers are applied in solution.

In contrast to EP-A1-256 933, according to which an application such as the spraying on of fenofibrate onto the polyvinylpyrrolidone acting solely as binding agent is carried out, in the process of the invention a mixing of the fenofibrate with the polyvinylpyrrolidone and in addition with cross-linked polyvinylpyrrolidone takes place. There is also the difference from EP-A1-256 933, in which no cross-linked polyvinylpyrrolidone is used, which is even excluded according to its process, because a binding agent that is soluble in water must be used, that in the process of the invention cross-linked polyvinylpyrrolidone particles must be obligatorily also mixed in. A further difference resides in the fact that according to the process of the

invention, in contrast to that of the cited publication, the granulation is performed with a surface-active agent in another stage.

The process of the invention differs from that of FR-A1-2 617 047 basically in that in the first one the surface-active agent is added by granulation and only after the fenofibrate particles are mixed with the polyvinylpyrrolidone particles and cross-linked polyvinylpyrrolidone. There is the further difference that the two last-mentioned substances are entirely lacking in the cited publication.

The invention differs basically from US patent 4,925,672, in which no process is described, in that it concerns the inventing of a process, and in addition in that in contrast to the cited publication, in which there is no mention of a content of cross-linked polyvinylpyrrolidone and a surface-active agent, even these substances are used.

An anionic agent or agents are preferably used as surface-active means. It is preferable to use an alkalialkylsulfate or alkalialkylsulfates, especially sodium laurylsulfate, as **anionic** surface-active agent or agents.

It is also preferable to use a polyvinylpyrrolidone with a K value of 10 to 96, especially 25 to 35, as polyvinylpyrrolidone.

It is furthermore preferable to use a cross-linked polyvinylpyrrolidone with a specific surface (BET) of 0.1 to 1.5 m^2/g, especially 0.5 to 1.5 m^2/g and quite particularly 0.7 to 1.1 m^2/g as cross-linked polyvinylpyrrolidone.

A fenofibrate with particle sizes of 100% = or < 20μm is preferably used.

It is also preferable to use a polyvinylpyrrolidone with particle sizes of 100% = or < 500µm as polyvinylpyrrolidone.

It is furthermore preferable to use a cross-linked polyvinylpyrrolidone with particles sizes of 100% = or < 500µm as cross-linked polyvinylpyrrolidone.

The fenofibrate is preferably used in constituent amounts of 65 to 85wt%, especially 70 to 80wt% relative to the dry granulate.

It is furthermore preferable to use the surface-active agent or agents in constituent amounts of 1.5 to 7wt%, especially 2 to 5wt% relative to the dry granulate.

It is also preferable to use the surface-active agent or agents in a concentration of 1 to 5wt%, especially 2 to 3wt%.

It is furthermore preferred to use the polyvinylpyrrolidone in constituent amounts of 2 to 6wt%, especially 3 to 5wt% relative to the dry granulate.

It is also preferable to use the cross-linked polyvinylpyrrolidone in constituent amounts of 10 to 30wt%, especially 15 to 25wt% relative to the dry granulate.

The other adjuvant or adjuvants optionally used can be customary in the pharmaceutical art. Examples are starch, microcrystalline cellulose, lactose and magnesium stearate. The mixing in of this other adjuvant or adjuvants to the fenofibrate is advantageously carried out together with the polyvinylpyrrolidone and cross-linked polyvinylpyrrolidone; however, it

can also take place in a later or earlier phase, but in these instances the simplification of the process is less.

According to an embodiment of the process of the invention the granulate obtained is filled into capsules, in particular hard gelatin capsules.

The drying of the granulate, advantageously down to a residual moisture content of at the most 2.5wt%, especially at the most 2.0wt%, and its filling into capsules that optionally takes place can be carried out in a known manner.

The granulates or capsules produced in this manner and with their action that is equally as good as that of those produced in accordance with the state of the art can be used successfully therapeutically, especially as lipid reducers.

The invention will now be explained in detail using the following example.

Example

A mixture of 90 kg micronized fenofibrate with particle sizes of 100% = or < 15µm and 97 to 95% = or < 5µm, 4.5 kg polyvinylpyrrolidone particles DAB 10 with a K value of 27 to 32 and with particles sizes of 95% = or < 250µm and 10% < 50µm and 22.5 kg cross-linked polyvinylpyrrolidone particles DAB 10 with a specific surface (BET) of 0.9 m^2/g and with particle sizes of at least 98% = or < 250µm and at the most

60% = or < 50µm is pressed through a 0.8 mm sieve and mixed 10 minutes. A solution of ~~2.274~~ **2.475** kg sodium laurylsulfate NF 18 and 101.25 kg purified water was prepared separately. The first-cited powder mixture was then granulated with the last-cited solution in a fluid-bed granulator with an inlet temperature of approximately 20 to 40°C (outlet temperature 20± 5°C). The moist granulate **was dried in a drier at a temperature of 50± 5°C to a residual moisture of about 1.5± 5%. The dry granulate** was pressed through a 0.5 mm sieve. The mixture was subsequently mixed 10 minutes longer.

The granulate obtained in this manner was filled in a capsule filling machine into opaque HS hard gelatin capsules No. 1 with a Turkish blue cap and a white body. ~~405,000~~ **450,000** capsules with a capsule content of 265 mg each were filled with the granulate with a total weight of 119.475 kg.

The determination of the scientifically recognized therapeutic target sizes C_{max}, t_{max} AUC_t and AUC yielded no significant deviation between the present fenofibrate preparation produced in accordance with the invention and the one produced according to example 1 of EP patent 330 532.

EXHIBIT 8

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re FENOFIBRATE PATENT LITIGATION	ECF Case No. 1:11-md-02241 (JSR)

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to the schedule established during the joint conference call with the Court on June 1, 2011, Plaintiff Lupin Atlantis Holdings S.A. ("LAH"), Plaintiff/Defendant Ethypharm S.A. ("Ethypharm"), and Defendants Paddock Laboratories, Inc., Cerovene, Inc., Mylan Inc., Mylan Pharmaceuticals, Inc., Ranbaxy Laboratories Limited, Ranbaxy Inc., Ranbaxy Pharmaceuticals, Inc., Apotex, Inc. and Apotex Corp. (collectively "Defendants"), by and through their attorneys, hereby set forth, in Exhibit A, each claim term, phrase, or clause in U.S. Patent No. 7,101,574 ("the '574 patent") and U.S. Patent No. 7,863,331 ("the '331 patent") that such party contends requires construction by the Court and each party's proposed construction of said claim terms, as well as definitions of claim terms on which the parties have reached agreement.

The parties agree that there will not be a need to present any expert testimony at the claim construction hearing set for August 1, 2011.

The '574 patent has 34 claims, two of which are independent claims, claims 1 and 19. The remaining dependent claims add additional limitations to those independent claims. The two independent claims are set forth below with the terms or phrases requested to be construed underlined:

1. A pharmaceutical composition in the form of granules, wherein each granule comprises a neutral microgranule on which is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant, and

wherein said fenofibrate is present in an amount greater than or equal to 60% by weight, relative to the weight of said pharmaceutical composition, and further wherein said binding cellulose derivative represents between 2 to 15% by weight, relative to the weight of said pharmaceutical composition.

19. A pharmaceutical composition in the form of granules, wherein each granule comprises a neutral microgranule on which is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization agent, wherein the mass ratio of said fenofibrate to said binding cellulose derivative is between 5/1 and 15/1.

The '331 patent has 4 claims, of which claim 1 is the sole independent claim. The remaining dependent claims add additional limitations to claim 1. Claim 1 is set forth below with the terms or phrases requested to be construed underlined:

1. A method of reducing food effect when treating hypertriglyceridemias and/or hypercholesterolemias and/or hyperlipidemias in a patient in need thereof comprising administering to said patient a therapeutically effective amount of a pharmaceutical composition comprising micronized fenofibrate, a surfactant and hydroxypropylmethylcellulose,
wherein said composition is in the form of granules comprising:

(a) a neutral core; and

(b) an active layer, surrounding the neutral core;

wherein said neutral core comprises a sugar or a sugar mixed with starch; said active layer comprises the micronized fenofibrate, the surfactant, and the binding cellulose derivative; and wherein the mass ratio of said fenofibrate to said hydroxypropylmethylcellulose is between 5/1 and 15/1, and said hydroxypropylmethylcellulose represents between 5 and 12% by weight of the composition.

EXHIBIT A

Claim Terms of The '574 Patent To Be Construed By The Court

Claim Term	LAH's/Ethypharm's Proposed Construction	Defendants' Proposed Construction
pharmaceutical composition	LAH and Ethypharm do not believe that any construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: a composition which is suitable for pharmaceutical use	all of the active and inactive ingredients in the final dosage form
said pharmaceutical composition	LAH and Ethypharm do not believe that any additional construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: the pharmaceutical composition in the form of granules, wherein each granule comprises a neutral microgranule on which is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent* *the underlined disputed terms are understood to incorporate LAH's/Ethypharm's proposed constructions as outlined below	all of the active and inactive ingredients in the final dosage form

granules	Neutral microgranules on which there is a mixture of micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent	many discrete granules
granule	Neutral microgranule on which there is a mixture of micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent	neutral microgranule on which is sprayed a suspension of micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent
each granule	No additional construction necessary	each and every granule in the pharmaceutical composition contains all the required ingredients
neutral microgranule	A therapeutically neutral substrate or region of a substrate	sugar or sugar mixed with starch particle having a size of between 200 and 1,000 microns and containing no fenofibrate
surfactant	A substance that lowers the surface tension of water	**One or more defendants propose the following construction:** a water-soluble substance, that when present in a sufficient amount and under appropriate conditions, increases the bioavailability of fenofibrate, and does not include anti-foaming agents such as simethicone **One or more defendants propose the following construction:** a water-dispersible amphiphilic organic compound that when present in a sufficient amount and under appropriate conditions, reduces the surface tension of water, and does not include anti-foaming agents such as simethicone

binding cellulose derivative as a solubilization adjuvant/agent	A cellulose-based polymer in said pharmaceutical composition that binds the micronized fenofibrate to the neutral microgranule and increases the micronized fenofibrate's solubility and/or rate of solubilization	any and all water-soluble cellulose-based polymer, such as HPMC, in the pharmaceutical composition that is capable of binding micronized fenofibrate to the neutral microgranule and increasing the micronized fenofibrate's solubility or rate of solubilization
micronized fenofibrate	Fenofibrate that has a smaller particle size than non-micronized fenofibrate such that it exhibits enhanced solubility and/or rate of solubilization when compared to non-micronized fenofibrate	fenofibrate particles of a size less than 15 microns free of other ingredients when micronized, and present in an aqueous suspension with one or more other ingredients when coated on the neutral core or neutral microgranule
wherein said fenofibrate is present in an amount greater than or equal to 60% by weight, relative to the weight of said pharmaceutical composition	weight of said micronized fenofibrate in said pharmaceutical composition divided by the weight of said pharmaceutical composition times 100 must be greater than or equal to 60[1]	weight of all of the micronized fenofibrate in the pharmaceutical composition divided by the weight of the pharmaceutical composition times 100 must be greater than or equal to 60
wherein said binding cellulose derivative represents between 2 to 15% by weight, relative to the weight of said pharmaceutical composition	weight of said binding cellulose derivative as a solubilization adjuvant/agent in said pharmaceutical composition divided by the weight of said pharmaceutical composition times 100 is between 2 to 15[2]	weight of all of the binding cellulose derivative in the pharmaceutical composition divided by the weight of the pharmaceutical composition times 100 is between 2 to 15

[1] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the terms "micronized fenofibrate" and "said pharmaceutical composition."

[2] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "binding cellulose derivative as a solubilization adjuvant/agent" and "said pharmaceutical composition."

wherein the mass ratio of said fenofibrate to said binding cellulose derivative is between 5/1 and 15/1	weight of said micronized fenofibrate in said pharmaceutical composition divided by the weight of binding cellulose derivative as a solubilization adjuvant/agent is between 5 and 15[3]	weight of all of the micronized fenofibrate divided by the weight of all of the binding cellulose derivative is between 5 and 15

[3] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "micronized fenofibrate" and "binding cellulose derivative as a solubilization adjuvant/agent."

Claim Terms of the '331 Patent To Be Construed By The Court

Claim Term	LAH's/Ethypharm's Proposed Construction	Defendants' Proposed Construction
pharmaceutical composition	LAH and Ethypharm do not believe that any construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: a composition which is suitable for pharmaceutical use	all of the active and inactive ingredients in the final dosage form
the composition	LAH and Ethypharm do not believe that any additional construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: the pharmaceutical composition comprising micronized fenofibrate, a surfactant and hydroxypropylmethylcellulose, wherein said composition is in the form of granules comprising: (a) a neutral core; and (b) an active layer* *the underlined disputed terms are understood to incorporate LAH's/Ethypharm's proposed constructions as outlined below	all of the active and inactive ingredients in the final dosage form
granules	Neutral cores on which there is micronized fenofibrate	many discrete granules

surfactant	A substance that lowers the surface tension of water	**One or more defendants propose the following construction:** a water-soluble substance, that when present in a sufficient amount and under appropriate conditions, increases the bioavailability of fenofibrate, and does not include anti-foaming agents such as simethicone **One or more defendants propose the following construction:** a water-dispersible amphiphilic organic compound that when present in a sufficient amount and under appropriate conditions, reduces the surface tension of water, and does not include anti-foaming agents such as simethicone
hydroxypropylmethylcellulose	A cellulose hydroxypropylmethyl ether that acts to bind the micronized fenofibrate to the neutral core and increases the micronized fenofibrate's solubility and/or rate of solubilization	the total of any and all grades of HPMC in the pharmaceutical composition
neutral core	A pharmaceutically neutral substrate to which active layer can be applied	same as neutral microgranule
active layer	A mixture of micronized fenofibrate, a surfactant, and hydroxypropylmethylcellulose	layer comprised of micronized fenofibrate, surfactant, and binding cellulose derivative sprayed on the outside of the neutral core
sugar	Lactose, mannitol, sucrose or other pharmaceutically acceptable monosaccharide or other lower oligosaccharide	lactose, mannitol, sucrose or other pharmaceutically acceptable monosaccharide or other lower oligosaccharide; not a starch or other polysaccharide

micronized fenofibrate	Fenofibrate that has a smaller particle size than non-micronized fenofibrate such that it exhibits enhanced solubility and/or rate of solubilization when compared to non-micronized fenofibrate	fenofibrate particles of a size less than 15 microns free of other ingredients when micronized, and present in an aqueous suspension with one or more other ingredients when coated on the neutral core or neutral microgranule
wherein the mass ratio of said fenofibrate to said hydroxypropylmethylcellulose is between 5/1 and 15/1	weight of said micronized fenofibrate in the composition divided by the weight of said hydroxypropylmethylcellulose in the composition is between 5 and 15[4]	weight of all of the micronized fenofibrate divided by the weight of all of the hydroxypropylmethylcellulose is between 5 and 15
said hydroxypropylmethylcellulose represents between 5 and 12% by weight of the composition	weight of said hydroxypropylmethylcellulose in the composition divided by the weight of the composition times 100 is between 5 to 12[5]	weight of all of the hydroxypropylmethylcellulose in the pharmaceutical composition divided by the weight of the pharmaceutical composition times 100 is between 5 and 12

Claim Terms Having a Definition To Which the Parties Have Agreed

Claim Term	Agreed Definition
binding cellulose derivative	hydroxypropylmethylcellulose[6]

[4] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "micronized fenofibrate," "the composition" and "hydroxypropylmethylcellulose."

[5] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "hydroxypropylmethylcellulose" and "the composition."

[6] To the extent the Court determines this term is capable of construction, Defendants do not propose a different construction. Defendants reserve their right to argue that this term lacks antecedent basis and renders the claim indefinite under 35 U.S.C. 112.

Dated: June 15, 2011

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EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

LUPIN ATLANTIS HOLDINGS S.A. and ETHYPHARM S.A., *Plaintiffs,* v. PADDOCK LABORATORIES, INC. and CEROVENE, INC., *Defendants.*	Case No. 1:11-cv-00668 (JSR)

PLAINTIFFS' ANSWER TO PADDOCK LABORATORIES, INC.'S COUNTERCLAIMS

Plaintiffs Lupin Atlantis Holdings S.A. ("Lupin Atlantis") and Ethypharm S.A. ("Ethypharm") (collectively, "Plaintiffs"), by their attorneys, respond as follows to the Counterclaims filed by Defendant Paddock Laboratories, Inc. ("Paddock"). Answers to Paddock's specific allegations are contained below in numbered paragraphs that correspond to the numbered paragraphs of Paddock's Counterclaims. Plaintiffs deny any allegations not expressly admitted in this Answer.

The Parties

66. Paddock is a corporation organized and existing under the laws of the State of Minnesota, with its headquarters and principal place of business at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427.

ANSWER: Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the allegations set forth in paragraph 66 of Paddock's Counterclaims and, therefore, deny them.

67. On information and belief, Lupin Atlantis Holdings S.A. is a corporation organized and existing under the laws of Switzerland, with a principal place of business at Bachstrasse 56, 8200 Schaffhausen SH, Switzerland.

ANSWER: Admitted by Lupin Atlantis and, upon information and belief, by Ethypharm, which does not contest this allegation.

68. On information and belief, Ethypharm S.A. is a corporation organized and existing under the laws of France, with its principal offices at 194 Bureaux de la Colline, 922 13 St. Cloud, France.

ANSWER: Admitted by Ethypharm and, upon information and belief, by Lupin Atlantis, which does not contest this allegation.

Jurisdiction and Venue

69. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 69 sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Defendants deny that this Court has subject matter jurisdiction over this action.

70. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and/or 2202.

ANSWER: Admitted.

71. Personal jurisdiction is proper in this Court as to Counterclaim-Defendants because they have subjected themselves to the jurisdiction of this Court by virtue of filing their Complaint.

ANSWER: Counterclaim-Defendants do not contest personal jurisdiction relative to the counterclaims asserted herein.

72. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), (c), (d), and/or 28 U.S.C. § 1400(b).

ANSWER: Counterclaim-Defendants do not contest venue relative to the counterclaims asserted herein.

73. There is an actual and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '574 patent.

ANSWER: Admitted.

Background

74. The '574 patent, entitled "Pharmaceutical Composition Containing Fenofibrate and the Preparation Method," issued on September 5, 2006, to Laboratories des Produits Ethiques Ethypharm.

ANSWER: Admitted.

75. Upon information and belief, Ethypharm is currently the owner of the '574 patent.

ANSWER: Admitted.

76. Upon information and belief, on or about May 7, 2001, Ethypharm and Ethypharm Industries S.A. and Reliant Pharmaceuticals LLC ("Reliant") entered into a development, license and supply agreement ("Ethypharm-Reliant license") which agreement includes a license under the '574 patent.

ANSWER: Admitted by Ethypharm and, upon information and belief, by Lupin Atlantis, which does not contest this allegation.

77. Upon information and belief, the Ethypharm-Reliant license imposes obligations to enforce the '574 patent.

ANSWER: Ethypharm admits that the Ethypharm-Reliant Agreement contains provisions relating to enforcement of the '574 patent, and denies the remaining allegations set forth in paragraph 77 of Paddock's Counterclaims. Lupin lacks sufficient knowledge or information to form a belief as to the truth of the allegations set forth in paragraph 77 of Paddock's Counterclaims and, therefore, denies them.

78. Upon information and belief, pursuant to the Ethypharm-Reliant license, Reliant sought and obtained United States Food and Drug Administration ("FDA") approval for, and marketed, sold, and distributed ANTARA® (micronized fenofibrate) capsules, 43 mg and 130 mg ("ANTARA® Product").

ANSWER: Admitted that Reliant obtained U.S. Food and Drug Administration ("FDA") approval for, and marketed, sold and distributed, 43 mg and 130 mg ANTARA® capsules. Ethypharm denies the remaining allegations set forth in paragraph 78 of Paddock's Counterclaims. Lupin lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations set forth in paragraph 78 of Paddock's Counterclaims and, therefore, denies them.

79. Upon information and belief, FDA approved ANTARA® under New Drug Application ("NDA") No. 21-695 on November 30, 2004 ("ANTARA® NDA").

ANSWER: Admitted.

80. Upon information and belief, Ethypharm is the party directly responsible for the development, manufacture, and entry of the ANTARA® Product into the fenofibrate market throughout the United States.

ANSWER: Admitted that ANTARA® currently is marketed throughout the United States. Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 80 of Paddock's Counterclaims and, therefore, deny them.

81. Upon information and belief, on or about August 2006, Reliant sold its rights under the '574 patent and to the ANTARA® Product to Oscient Pharmaceuticals Corporation ("Oscient") ("Ethypharm-Oscient license").

ANSWER: Admitted that in or about 2006, an agreement was reached between Reliant and Guardian II Acquisition Corporation ("Guardian") and Oscient Pharmaceuticals Corporation ("Oscient") in which certain rights concerning ANTARA® were transferred to one or both of the latter two entities. Plaintiffs lack sufficient

knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 81 of Paddock's Counterclaims and, therefore, deny them.

82. Upon information and belief, Oscient assumed Reliant's duties and obligations under the Ethypharm-Reliant license, including but not limited to the obligation to launch and promote, and otherwise commercialize, the ANTARA® Product throughout the United States, including the State of New Jersey.

ANSWER: Admitted that as part of the 2006 agreement, Guardian and Oscient acquired certain rights from Reliant concerning ANTARA®. Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 82 of Paddock's Counterclaims and, therefore, deny them.

83. Upon information and belief, the Ethypharm-Oscient license agreement imposes obligations to enforce the '574 patent.

ANSWER: Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 83 of Paddock's Counterclaims and, therefore, deny them.

84. Upon information and belief, Ethypharm, by virtue of the Ethypharm-Reliant license, caused FDA to list the '574 patent in FDA's publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the *Orange Book*") in connection with ANTARA®.

ANSWER: Ethypharm admits, and Lupin Atlantis admits upon information and belief and does not contest, that a request was submitted to the FDA to list the '574 patent in FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book") in connection with ANTARA®. Plaintiffs deny any remaining allegations set forth in paragraph 84 of Paddock's Counterclaims.

85. Upon information and belief, Counterclaim-Defendants continue to maintain the listing of the '574 patent in the *Orange Book* in connection with ANTARA®.

ANSWER: Plaintiffs admit that the '574 patent currently is listed in the Orange Book in connection with ANTARA®. Plaintiffs deny any remaining allegations set forth in paragraph 85 of Paddock's Counterclaims.

86. Ethypharm filed a lawsuit asserting the '574 patent against Lupin, which had previously sought FDA approval to market generic fenofibrate capsules based on the ANTARA® NDA. *Oscient Pharms. Corp., Guardian II Acquisition Corp. and Ethypharm S.A. v. Lupin Ltd and Lupin Pharmaceuticals, Inc.*, No. 090083 (D. Md. filed Jan. 14, 2009) ("the Lupin Action"). In their Answer to the Complaint, Lupin asserted that the claims of the '574 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq.*

ANSWER: Admitted that Ethypharm, Oscient, and Guardian brought an infringement action against Lupin Limited and Lupin Pharmaceuticals, Inc. (Civil Action No. 09-0083, D. Md., filed January 14, 2009) in which the '574 patent was asserted, and that Lupin Limited and Lupin Pharmaceuticals Inc. asserted that the claims of the '574 patent were invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq*. Plaintiffs deny any remaining allegations set forth in paragraph 86 of Paddock's Counterclaims.

87. Upon information and belief, Lupin was the first generic applicant to file an ANDA seeking FDA approval to market generic fenofibrate capsules based on the ANTARA® NDA ("Lupin's ANDA"). Upon information and belief, as part of defendant Lupin's ANDA, Lupin included a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) that the '574 patent will not be infringed and/or the '574 patent is invalid ("Lupin's Paragraph IV Certification").

ANSWER: Admitted that Lupin Limited was the first applicant to file an Abbreviated New Drug Application ("ANDA") to commercialize generic versions of ANTARA®, and that Lupin Limited included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) asserting that the '574

patent would not be infringed and/or was invalid. Plaintiffs deny any remaining allegations set forth in paragraph 87 of Paddock's Counterclaims.

88. Upon information and belief, the Lupin action was brought within the statutory 45-day period, staying FDA from granting final approval to Lupin's ANDA for 30 months subject to certain conditions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

ANSWER: Admitted that the infringement action against Lupin Limited and Lupin Pharmaceuticals, Inc. was brought within the statutory 45-day period set forth in 21 U.S.C. § 355(j)(5)(B)(iii), and that this statute provides that approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph Section 355(j)(2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action. Paragraph 88 otherwise sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Plaintiffs deny them.

89. Upon information and belief, on or about July 2009, Oscient and its wholly owned subsidiary, Guardian II Acquisition Corporation, each filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts.

ANSWER: Admitted that Oscient and Guardian filed for bankruptcy in or about 2009, but Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 89 of Paddock's Counterclaims and, therefore, deny them.

90. Upon information and belief, on or about September 2009, defendant Lupin successfully bid to acquire Oscient's rights under the '574 patent, the ANTARA® NDA, and to the ANTARA® Product under the procedures of the United States Bankruptcy Court.

ANSWER: Admitted that Lupin Atlantis, in or about September 2009, acquired rights under the '574 patent, the ANTARA® New Drug Application ("NDA") and certain

rights relating to ANTARA®. Plaintiffs deny any remaining factual allegations set forth in paragraph 90 of Paddock's Counterclaims.

91. Upon information and belief, on or about September 2009, defendant Lupin acquired Oscient's rights under the '574 patent, the ANTARA® NDA, and to the ANTARA® Product under the procedures of the United States Bankruptcy Court. Lupin asserts that Lupin Atlantis is currently the named holder of the ANTARA® NDA.

ANSWER: Admitted that Lupin Atlantis, in or about September 2009, acquired rights under the '574 patent, the ANTARA® NDA, and certain rights relating to ANTARA®, and that Lupin Atlantis currently is the owner of the ANTARA® NDA. Plaintiffs deny any remaining factual allegations set forth in paragraph 91 of Paddock's Counterclaims.

92. Upon information and belief, on or about September 2009, Dr. Reddy's Laboratories Ltd. ("DRL") acquired the rights to Lupin's ANDA, including the right to market generic fenofibrate capsules under Lupin's ANDA some time prior to August 20, 2020, the expiration date of the '574 patent.

ANSWER: Lupin Atlantis admits that in or about September 2009, Dr. Reddy's Laboratories Ltd. ("DRL") acquired rights to Lupin Limited's ANDA directed to generic versions of ANTARA®, including the right to market generic versions of ANTARA® described in Lupin Limited's ANDA prior to August 20, 2020. Lupin Atlantis denies any other factual allegations set forth in paragraph 92 of Paddock's Counterclaims. Ethypharm lacks sufficient knowledge or information to form a belief as to the truth of the allegations set forth in paragraph 92 of Paddock's Counterclaims and, therefore, denies them.

93. Upon information and belief, on or about October 2009, the Lupin action was settled.

ANSWER: Admitted.

94. As a result, DRL may be entitled to a generic marketing exclusivity period during which FDA may not approve other generic fenofibrate capsule ANDAs based on the ANTARA® NDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

ANSWER: Paragraph 94 sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Plaintiffs deny them.

95. Upon information and belief, the '574 patent continues to be listed in the *Orange Book* in connection with ANTARA®.

ANSWER: Admitted that the '574 patent currently is listed in the FDA Orange Book in connection with ANTARA®.

96. Paddock filed ANDA No. 91-362 ("Paddock's ANDA") seeking FDA approval to market generic fenofibrate capsules, 43 mg and 130 mg, based on the ANTARA® NDA ("Paddock's Proposed Product"). As part of Paddock's NDA, Paddock included a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) that the '574 patent will not be infringed by Paddock's Proposed Product, and/or the '574 patent is invalid, and seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Paddock's Proposed Product prior to the expiration of the '574 patent ("Paddock's Paragraph IV Certification").

ANSWER: Admitted that Paddock purports to have filed ANDA No. 91-362 ("Paddock's ANDA") which allegedly seeks FDA approval to market generic fenofibrate capsules, 43 mg and 130 mg, based on the ANTARA® NDA. It is further admitted that Paddock asserts that, as part of Paddock's ANDA, Paddock included a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) that the '574 patent will not be infringed by the products described in Paddock's ANDA, and/or the '574 patent is invalid, and that Paddock seeks FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the product described in Paddock's ANDA prior to the expiration of the '574 patent. Plaintiffs lack sufficient knowledge or information to

form a belief as to the truth of the remaining allegations in paragraph 96 of Paddock's Counterclaims and, therefore, deny them.

97. Paddock provided notice of its Paragraph IV Certification by letter addressed to Ethypharm and Oscient dated May 15, 2009, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("Paddock's Notice Letter"). Paddock's Notice Letter was accompanied by an offer of confidential access to Paddock's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) for the purpose of determining whether an infringement action should be brought.

ANSWER: Admitted that Ethypharm received a letter dated May 15, 2009 addressed to Ethypharm and Oscient, which Paddock alleges constitutes notice of its alleged certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), this letter further allegedly including what Paddock purports to be an offer of confidential access to Paddock's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Paragraph 97 also sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Plaintiffs deny them.

98. Upon information and belief, Ethypharm and Oscient received Paddock's Notice Letter on or about May 26, 2009.

ANSWER: Admitted that Ethypharm received a letter dated May 15, 2009 addressed to Ethypharm and Oscient, which Paddock alleges constitutes notice of its alleged certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4). Lupin Atlantis lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 98 of Paddock's Counterclaims and, therefore, denies them.

99. Paddock's Notice Letter initiated a 45-day statutory period during which Ethypharm and/or Oscient had the opportunity to file an action for patent infringement.

ANSWER: Paragraph 99 sets forth a legal conclusion to which no answer is required. To the extent an answer to any factual allegation set forth therein is required, Plaintiffs deny them.

100. Before the 45-day statutory period expired, Paddock provided a confidential copy of Paddock's ANDA to counsel for Ethypharm and Oscient.

ANSWER: Ethypharm admits that documents selected by Paddock which, as alleged by Paddock, constituted portions of Paddock's ANDA were provided to Ethypharm's prior counsel on a confidential basis. Ethypharm otherwise denies the allegations set forth in paragraph 100. Lupin Atlantis lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 100 of Paddock's Counterclaims and, therefore, denies them.

101. Ethypharm and Oscient did not bring an action for patent infringement before the 45-day period expired.

ANSWER: Admitted that Ethypharm and Oscient did not bring an action against Paddock asserting infringement of the '574 patent.

102. On July 30, 2009, Paddock filed an action in the United States District Court for the District of New Jersey, Case No. 3:09-cv-03779-GEB-LHG ("New Jersey Action"), against Ethypharm seeking, among other things, a declaratory judgment that Paddock's ANDA No. 91-362 did not infringe the '574 patent.

ANSWER: Admitted.

103. Lupin Limited, Lupin Pharmaceuticals, Inc. and Lupin Atlantis Holdings, S.A. were later added as defendants in the New Jersey Action.

ANSWER: Admitted.

104. No defendant in the New Jersey Action, including Ethypharm and Lupin, alleged in that lawsuit that Paddock's ANDA or Paddock's Proposed Product infringed the '574 patent.

ANSWER: Plaintiffs admit that prior to dismissal of the New Jersey Action, Ethypharm and Lupin Atlantis did not allege a counterclaim that Paddock's Proposed Product, as described in ANDA No. 91-362 as originally filed with the FDA, infringed the '574 patent. Plaintiffs deny any remaining allegations set forth in paragraph 104 of Paddock's Counterclaims.

105. In late 2010, Paddock filed a new Paragraph IV certification in connection with its ANDA No. 91-362.

ANSWER: Plaintiffs admit that, in late 2010, Paddock purportedly filed a new Paragraph IV certification in connection with its ANDA No. 91-362. Plaintiffs deny any remaining allegations set forth in paragraph 105 of Paddock's Counterclaims.

106. On December 20, 2010, Paddock provided notice of its new Paragraph IV Certification by letter addressed to Ethypharm, Lupin and others, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("Paddock's Second Notice Letter"). Paddock's Second Notice Letter was accompanied by an offer of confidential access to Paddock's ANDA pursuant to 21 U.S.C. § 355 (j)(5)(C)(i)(III) for the purpose of determining whether an infringement action should be brought.

ANSWER: Admitted that Ethypharm and Lupin Atlantis received an undated letter on or about December 21, 2010, addressed to Ethypharm, Lupin Atlantis, and others, which Paddock alleges constitutes notice of its alleged certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), this letter further allegedly including what Paddock purports to be an offer of confidential access to Paddock's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Paragraph 106 also sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Plaintiffs deny them.

107. On information and belief, Lupin and Ethypharm received Paddock's Second Notice Letter on or about December 21, 2010.

ANSWER: Admitted that Ethypharm and Lupin Atlantis received an undated letter on or about December 21, 2010, addressed to Ethypharm, Lupin Atlantis, and

others, which Paddock alleges constitutes notice of its alleged certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), this letter further allegedly including what Paddock purports to be an offer of confidential access to Paddock's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Paragraph 107 also sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Plaintiffs deny them.

108. On January 18, 2011, the United States District Court for the District of New Jersey dismissed the New Jersey Action without prejudice for lack of subject matter jurisdiction.

ANSWER: Admitted.

109. At the time they received Paddock's Second Notice Letter, Lupin and Ethypharm were in possession of sufficient information to determine whether they could file a new lawsuit alleging that Paddock's Proposed Product infringes the '574 patent, including Paddock's entire ANDA and related regulatory correspondence all of which were provided to counsel for Lupin and Ethypharm in the New Jersey Action.

ANSWER: Plaintiffs admit that counsel for Lupin Atlantis and Ethypharm was in possession of what Paddock purported to be Paddock's entire ANDA and related regulatory correspondence, which was protected from disclosure to any in-house members of Ethypharm and Lupin Atlantis by the protective order entered in the New Jersey Action. Plaintiffs deny any remaining allegations set forth in paragraph 109 of Paddock's Counterclaims.

110. Upon information and belief, counsel for Lupin and Ethypharm in the New Jersey Action (Leydig, Voit & Mayer , Ltd.) were experienced in patent law and were able to compare Paddock's ANDA to the claims of the '574 patent to determine whether the products described in the ANDA would infringe those claims under 35 U.S.C. § 271(e)(2).

ANSWER: Plaintiffs admit that its counsel in the New Jersey Action (Leydig, Voit & Mayer, Ltd.) is experienced in patent law, but deny the remaining allegations of paragraph 110 of Paddock's Counterclaims.

111. Leydig, Voit & Mayer, Ltd. also represents Lupin in this litigation.

ANSWER: Plaintiffs admit that Lupin Atlantis is represented by Leydig, Voit & Mayer, Ltd. in this litigation, but deny the remaining allegations of paragraph 111 of Paddock's Counterclaims.

112. All claims of the '574 patent contain a limitation that requires a "pharmaceutical composition in the form of granules, wherein each granule comprises a neutral microgranule…."

ANSWER: Admitted.

113. According to Paddock's ANDA, Paddock's Proposed Product does not contain any neutral microgranules.

ANSWER: Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 113 of Paddock's Counterclaims and, therefore, deny them.

114. According to Paddock's ANDA, Paddock's Proposed Product also does not satisfy other limitations of the '574 patent.

ANSWER: Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 114 of Paddock's Counterclaims and, therefore, deny them.

115. For example, according to Paddock's ANDA, Paddock's Proposed Product does not contain at least 60% by weight micronized fenofibrate.

ANSWER: Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 115 of Paddock's Counterclaims and, therefore, deny them.

116. For example, according to Paddock's ANDA, Paddock's Proposed Product does not contain between 2 to 15% by weight cellulose derivative.

ANSWER: Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 116 of Paddock's Counterclaims and, therefore, deny them.

117. For example, according to Paddock's ANDA, Paddock's Proposed Product does not contain a mass ratio of fenofibrate to cellulose derivative between 5/1 and 15/1.

ANSWER: Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 117 of Paddock's Counterclaims and, therefore, deny them.

118. Every claim of the '574 patent includes at least one of the limitations discussed above in paragraphs 115 through 117.

ANSWER: Plaintiffs admit that the claims of the '574 patent include at least one of the following limitations: (1) "wherein said fenofibrate is present in an amount greater than or equal to 60% by weight of said pharmaceutical composition;" (2) "wherein said binding cellulose derivative represents between 2 to 15% by weight, relative to the weight of said pharmaceutical composition;" and (3) "wherein the mass ratio of said fenofibrate to said binding cellulose derivative is between 5/1 and 15/1." Plaintiffs deny any remaining factual allegations set forth in paragraph 118 of Paddock's Counterclaims.

119. Paddock's Proposed Product thus infringes none of the claims of the '574 patent.

ANSWER: Denied.

120. On January 31, 2011, Lupin and Ethypharm nonetheless filed this instant suit alleging infringement of the '574 patent.

ANSWER: Plaintiffs admit that the instant action was filed on January 31, 2011. Plaintiffs deny any remaining factual allegations set forth in paragraph 120 of Paddock's Counterclaims.

121. At the time Lupin and Ethypharm filed their Complaint in this action, they knew that Paddock's Proposed Product would not infringe any of the claims of the '574 patent. This action was filed for an improper purpose.

ANSWER: Denied.

Count I – Declaratory Judgment of Non-Infringement of the '574 Patent

122. Paddock incorporates by reference the allegations in Paragraphs 65-121 of its counterclaims.

ANSWER: Plaintiffs reassert their responses to paragraphs 65-121 as if fully set forth herein.

123. The manufacture, use, offering for sale or importation of Paddock's Proposed Product will not infringe, directly or indirectly, any valid and enforceable claim of the '574 patent.

ANSWER: Paragraph 123 sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Plaintiffs deny them.

124. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale or importation of Paddock's Proposed Product will infringe the '574 patent.

ANSWER: Admitted.

125. Paddock is entitled to a judicial declaration that the manufacture, use, offer for sale, sale and importation of Paddock's Proposed Product do not and will not infringe any valid claim of the '574 patent.

ANSWER: Paragraph 125 sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Plaintiffs deny them.

Count II – Declaratory Judgment of Invalidity of the '574 Patent

126. Paddock incorporates by reference the allegations in Paragraphs 65-121 of its counterclaims.

ANSWER: Plaintiffs reassert their responses to paragraphs 65-121 as if fully set forth herein.

127. On information and belief, the claims of the '574 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one of more of §§ 101, 102, 103, 111, 112, 116, 132, 135, 256, and 287.

ANSWER: Denied.

128. There is an actual and justiciable controversy between the parties concerning whether the '574 patent is valid.

ANSWER: Admitted.

129. Paddock is entitled to a judicial declaration that the '574 patent is invalid.

ANSWER: Paragraph 129 sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Plaintiffs deny them.

Respectfully submitted,

/s Joseph V. DeMarco

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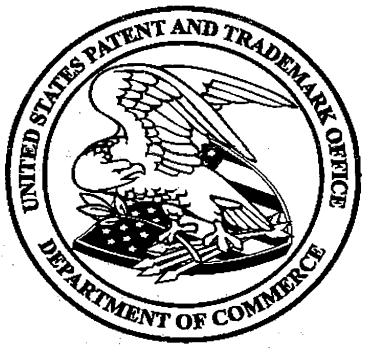
EXHIBIT 10

Manual of PATENT EXAMINING PROCEDURE

Original Eighth Edition, August 2001
Latest Revision July 2010



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Revision 2, May 2004
Revision 3, August 2005
Revision 4, October 2005
Revision 5, August 2006
Revision 6, September 2007
Revision 7, July 2008
Revision 8, July 2010

201.07 Continuation Application [R-3]

A continuation is a second application for the same invention claimed in a prior nonprovisional application and filed before the original prior application becomes abandoned or patented. The continuation application may be filed under 37 CFR 1.53(b) (or 1.53(d) if the application is a design application). The applicant in the continuation application must include at least one inventor named in the prior nonprovisional application. The disclosure presented in the continuation must be the same as that of the original application; i.e., the continuation should not include anything which would constitute new matter if inserted in the original application. The continuation application must claim the benefit of the prior nonprovisional application under 35 U.S.C. 120 or 365(c). >For more information on claiming the benefit of a prior nonprovisional application, see MPEP § 201.11.<

An application claiming the benefits of a provisional application under 35 U.S.C. 119(e) should not be called a "continuation" of the provisional application since an application that claims benefit of a provisional application is a nonprovisional application of a provisional application, not a continuation, division, or continuation-in-part of the provisional application.

At any time before the patenting or abandonment of or termination of proceedings on his or her earlier nonprovisional application, an applicant may have recourse to filing a continuation in order to introduce into the application a new set of claims and to establish a right to further examination by the primary examiner. *>A continued prosecution< application >(CPA)< under 37 CFR 1.53(d) >(available only for design applications)<, however, must be filed prior to payment of the issue fee unless a petition under 37 CFR 1.313(c) is granted in the prior application. In addition, a continuation or divisional application may only be filed under 37 CFR 1.53(d) if the prior nonprovisional application is a design application that is complete as defined by 37 CFR 1.51(b).

For notation to be put in the file history by the examiner in the case of a continuation application, see MPEP § 202.02.

Use form paragraph 2.05 to remind applicant of possible continuation status.

¶ *2.05 Possible Status as Continuation*

This application discloses and claims only subject matter dis closed in prior application no **[1]**, filed **[2]**, and names an inventor or inventors named in the prior application. Accordingly, this application may constitute a continuation or division. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Examiner Note:

1. This form paragraph should only be used if it appears that the application may be a continuation, but priority has not been prop erly established.

2. An application claiming the benefits of a provisional applica tion under 35 U.S.C. 119(e) should not be called a "continuation" of the provisional application since an application that claims ben efit of a provisional application is a nonprovisional application of a provisional application, not a continuation, division, or continu ation in part of the provisional application.

201.08 Continuation-in-Part Application [R-3]

A continuation-in-part is an application filed during the lifetime of an earlier nonprovisional application, repeating some substantial portion or all of the earlier nonprovisional application and *adding matter not disclosed* in the said earlier nonprovisional application. (*In re Klein*, 1930 C.D. 2, 393 O.G. 519 (Comm'r Pat. 1930)). The continuation-in-part application may only be filed under 37 CFR 1.53(b). The continuation-in-part application must claim the benefit of the prior nonprovisional application under 35 U.S.C. 120 or 365(c). >For more information on claiming the benefit of a prior nonprovisional application, see MPEP § 201.11.<

A continuation-in-part application CANNOT be filed as a continued prosecution application (CPA) under 37 CFR 1.53(d).

An application claiming the benefit of a provisional application under 35 U.S.C. 119(e) should not be called a "continuation-in-part" of the provisional application since an application that claims benefit of a provisional application is a nonprovisional application of a provisional application, not a continuation, division, or continuation-in-part of the provisional application.

The mere filing of a continuation-in-part does not itself create a presumption that the applicant acquiesces in any rejections which may be outstanding in the copending national nonprovisional application or

applications upon which the continuation-in-part application relies for benefit.

A continuation-in-part filed by a sole applicant may also derive from an earlier joint application showing a portion only of the subject matter of the later application, subject to the conditions set forth in 35 U.S.C. 120 and 37 CFR 1.78. Subject to the same conditions, a joint continuation-in-part application may derive from an earlier sole application.

Unless the filing date of the earlier nonprovisional application is actually needed, for example, in the case of an interference or to overcome a reference, there is no need for the Office to make a determination as to whether the requirement of 35 U.S.C. 120, that the earlier nonprovisional application discloses the invention of the second application in the manner provided by the first paragraph of 35 U.S.C. 112, is met and whether a substantial portion of all of the earlier nonprovisional application is repeated in the second application in a continuation-in-part situation. Accordingly, an alleged continuation-in-part application should be permitted to claim the benefit of the filing date of an earlier nonprovisional application if the alleged continuation-in-part application complies with the **>other< requirements of 35 U.S.C. 120 >and 37 CFR 1.78, such as<:

(A) The first application and the alleged continuation-in-part application were filed with at least one common inventor;

(B) The alleged continuation-in-part application was "filed before the patenting or abandonment of or termination of proceedings on the first application or an application similarly entitled to the benefit of the filing date of the first application"; and

(C) The alleged continuation-in-part application "contains or is amended to contain a specific reference to the earlier filed application." (The specific reference **>must be submitted either in the first sentence(s) of the specification or in an application data sheet (see 37 CFR 1.76(b)(5)).)

See MPEP § 201.11 for more information on claiming the benefit of a prior nonprovisional application.<

For notation to be put in the file history by the examiner in the case of a continuation-in-part application see MPEP § 202.02. See MPEP § 708 for order of examination.

Use form paragraph 2.06 to remind applicant of possible continuation-in-part status.

¶ *2.06 Possible Status as Continuation in Part*

This application repeats a substantial portion of prior Application No. **[1]**, filed **[2]**, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation in part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Examiner Note:

1. This form paragraph should only be used when it appears that the application may qualify as a continuation in part, but no priority claim has been perfected.
2. An application claiming the benefits of a provisional application under 35 U.S.C. 119(e) should not be called a "continuation in part" of the provisional application since an application that claims benefit of a provisional application is a nonprovisional application of a provisional application, not a continuation, division, or continuation in part of the provisional application.

201.09 Substitute Application [R-5]

The use of the term "Substitute" to designate any application which is in essence the duplicate of an application by the same applicant abandoned before the filing of the later application, finds official recognition in the decision *Ex parte Komenak*, 45 USPQ 186, 1940 C.D. 1, 512 O.G. 739 (Comm'r Pat. 1940). Current practice does not require applicant to insert in the specification reference to the earlier application; however, attention should be called to the earlier application. The notation in the file history (see MPEP § 202.02) that one application is a "Substitute" for another is printed in the heading of the patent copies. See MPEP § 202.02.

As is explained in MPEP § 201.11, a "Substitute" does not obtain the benefit of the filing date of the prior application.

Use form paragraph 2.07 to remind applicant of possible substitute status.
**>

¶ *2.07 Definition of a Substitute*

Applicant refers to this application as a "substitute" of Application No. **[1]**, filed **[2]**. The use of the term "substitute" to designate an application which is in essence the duplicate of an application by the same applicant abandoned before the filing of the later case finds official recognition in the decision, *Ex parte Komenak*, 45 USPQ 186, 1940 C.D. 1, 512 O.G. 739 (Comm'r Pat. 1940). The notation on the file wrapper (See MPEP § 202.02) that one case is a "substitute" for another is printed in the